

REMARKS

Claims 1-57 are pending. Claims 6, 7, 10-13, 21 and 22 have been withdrawn. Claims 1, 3-5, 8-9, 14-16, 18-20, 23, 31-32, 34 are currently amended. Claims 2, 17, 29-30 and 41-42 are cancelled. New claims 46-57 have been added. No new matter is believed to be added by this amendment. In addition, unless a passage of an amendment is specifically discussed below in connection with one or more cited references, applicants respectfully submit that the remarks accompanying this amendment should be constructed as being submitted merely to clarify the invention rather than as a limitation submitted to overcome a cited reference.

Claim rejection under 35 U.S.C. §112

Claim 18 was rejected because of a typographical error and due to a phrase having insufficient antecedent basis. In response, applicants have amended Claim 18 to read as follows:

18. The system of claim 1, wherein the energy emitter apparatus further comprises a controller and a sensor coupled to the controller, wherein the sensor detects when the energy emitter apparatus is in position on the tissue interface member, and wherein the controller is responsive to the sensor to enable activation of the energy emitter apparatus.

Claim Rejections under 35 U.S.C. §102

Claims 1, 8-9, 14 and 41 were rejected as being anticipated by U.S. Patent No. 4,274,418 to Vesterager *et al.* Further, Claims 1, 8-9, 14, 17 and 42 were rejected as being anticipated by U.S. Patent No. 5,879,373 to Roper *et al.* Still further, Claims 1, 8-9, 14-15, 17 and 42 were rejected as being anticipated by U.S. Patent No. 6,381,489 to Ashibe. Additionally, the examiner rejected Claims 1, 8-9, 17-19 and 42 as being anticipated by U.S. Patent No. 5,556,372 to Talish *et al.* Finally, Claims 1, 8-9, 14, 16, 23-24, 29-30, 32-33 and 41 were rejected by the examiner as being anticipated by U.S. Patent No. 5,568,806 to Cheney, II *et al.*

Based on the amendments to independent Claims 1, 23 and 32, applicants respectfully traverses these rejections. Differences exist between the present invention, as claimed in independent Claims 1, 23 and 32 as currently amended, and the invention disclosed and taught by cited prior art. Thus, the cited prior art cannot anticipate amended independent Claims 1, 23 and 32.

As amended, independent Claims 1, 23, and 32 read as follows:

1. A system comprising an alignment device for aligning at least one apparatus with respect to a surface of a tissue, the alignment device comprising a tissue interface member suitable for positioning on the surface of the tissue and mating with the apparatus to maintain alignment of the apparatus during an operation of the apparatus, the alignment device further comprising a removable energy absorbing layer attached to the tissue interface member, wherein the energy absorbing layer is responsive to energy directed thereon to heat up and to conductively transfer heat to the surface of the tissue to ablate the tissue to cause tissue ablation, and wherein the apparatus is an energy emitter apparatus including at least one energy source for emitting energy, wherein the energy emitter apparatus includes at least one alignment member that mates with the tissue interface member to achieve alignment with the tissue, so that, when the heat is transferred to the tissue, the layer may be removed to expose the ablated tissue.

23. A system comprising:
a tissue interface member suitable for positioning on the surface of the tissue;
a tissue breaching device that mates with the tissue interface member to achieve a desired alignment with the surface of the tissue, wherein the tissue breaching apparatus forms at least one opening in the tissue; and
a sensor device capable of mating to the tissue interface member when the tissue breaching device is not mated to the tissue interface member so that the sensor device is aligned with the at least one opening in the tissue,
wherein the sensor device collects a biological fluid by the force of a pressure differential between the at least one opening and sensor device, and wherein the sensor device detects a characteristic of a biological fluid collected from the at least one opening in the tissue.

32. A method for detecting a characteristic of a biological tissue, comprising the steps of:
placing a tissue interface member at a desired position onto the surface of the tissue;
mating a tissue breaching apparatus to the tissue interface member to achieve alignment with the surface of the tissue;
activating the tissue breaching apparatus to form a breached tissue site;
detaching the tissue breaching apparatus from the tissue interface member;
positioning an energy absorbing layer proximate to the surface of the tissue in alignment with the tissue interface member;
removing the energy absorbing layer; and
mating a sensor device to the tissue interface member to achieve alignment with the breached tissue site.

As amended, independent Claim 1 includes a removable energy absorbing layer. The energy absorbing layer aids in the precision of the ablation of the tissue. The removal of the layer exposes the ablated area of the tissue so that further investigations and/or actions may be taken on/from the ablated area. None of the cited prior art shows this feature.

As amended, independent Claim 23 includes the alignment of the tissue breaching device and a sensor device and where the fluid is withdrawn by an applied pressure differential. It is noted that “suction” in Claim 25 was considered allowable. The present claim differs only in that suction has been replaced by a broader term “pressure differential.” Applicants further submit that the definition in the specification already establishes such a broader interpretation of the term “suction.” Consequently, Claim 23 should be inherently allowable.

Finally, independent Claim 32 has been amended to add the removal of the energy absorbing layer. As noted above, none of the cited prior art has or teaches the removal of the layer exposes the ablated area of the tissue so that further investigations and/or actions may be taken on/from the ablated area. None of the cited prior art shown this feature.

The Federal Circuit has held that "[a] claim is anticipated only if each and every element *as set forth in the claim* is found, either expressly or inherently described, in a single prior art reference." *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1570 (Fed. Cir. 1988) (quoting *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771, 218 U.S.P.Q. 781, 789 (Fed. Cir. 1983)) (emphasis in original). Therefore, applicants respectfully request that the Examiner withdraw the Section 102 rejection of independent Claims 1, 23 and 32.

Claim Rejections under 35 U.S.C. §103

Claims 1-5 were rejected as being obvious over U.S. Patent No. 5,885,211 to Eppstein *et al.* in view of U.S. Patent 5,671,317 to Weishaupt *et al.* Based on the amendments to independent Claim 1, applicants respectfully traverses these rejections. Eppstein teaches microporation but provides no alignment feature and Weishaupt is merely a tripod that likewise has no relation to an energy absorbing layer. The prior art does not have a removable energy absorbing layer. Accordingly, one skilled in the art would not have been motivated to modify the cited references to arrive at the claimed invention having a removable energy absorbing layer because there is no teaching to make the modification. Nor is there any suggestion of such a design. Thus, a modification to use a removable energy absorbing layer would require hindsight reasoning, which the Federal Circuit has explicitly rejected. *See In re Fritch*, 972 F.2d 1260, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992) ("Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious."). Therefore, in addition to not being anticipated by the cited references, independent Claim 1, as amended, likewise would not be rendered obvious by Eppstein and Weishaupt.

Allowable Subject Matter

On page 8 of the Office Action, applicants thank the Examiner for the indicated allowable subject matter of dependent Claims 20, 25-28, 31 and 34-40. Accordingly, applicants have added new independent Claim 44 that includes the subject matter of Claims 1, 19 and 20. Further, applicants have added new independent Claim 45 that includes the subject matter of Claims 23-25. Applicants have also added new independent Claim 46 that includes the subject matter of Claims 32-34.

New Claims

Applicants have added new Claims 43-57. New Claims 44-46 were discussed above. Support for the new claims may be found throughout the Specification. New Claim 43 includes the subject matter of allowable new Claim 45. New Claim 47 depends from allowable currently amended Claim 1. Claims 48-50 depend from new Claim 47. New Claim 51 is similar in scope to allowable currently amended Claim 32 (with a substance delivery apparatus instead of a sensor device). Claims 52-56 depend from new Claim 51. New Claim 56 is similar in scope to allowable new Claim 45 (with a substance delivery apparatus claimed instead of a sensor device). New Claim 57 is similar in scope to allowable new Claim 46 (with a substance delivery apparatus claimed instead of a sensor device). Thus, new Claims 43-57 should be in condition for allowance.

Claims 3-5, 8-9, 16, 18-20 and 31 have been amended to clarify the respective claim, correct typographical errors, and/or to correct dependency. Claims 14 and 15 have been amended to clarify that the adhesive element or strap aids in maintaining the alignment of the apparatus with respect to the surface of the tissue. Further, Claim 34 clarifies that the energy absorbing layer is removed substantially simultaneously as the energy emitter device is detached.

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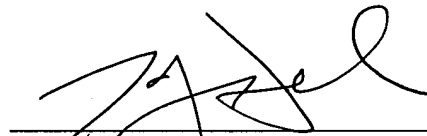
Confirmation No. 7089

Response to Office Action

Therefore, applicants respectively request allowance of all the outstanding claims. The Examiner is invited and encouraged to contact directly the undersigned if such contact may enhance the efficient prosecution of this application to issue.

Payment in the amount of \$501.00 representing \$55.00 for a one-month extension of time fee and \$301.00 for the net addition of 7 independent claims and \$145.00 for the addition of 2 dependent claims is to be charged to a credit card and such payment is authorized by the signed, enclosed document entitled: Credit Card Payment Form PTO-2038. No additional fees are believed to be due; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

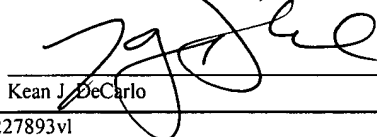


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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: MAIL STOP AMENDMENT, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on July 15, 2004.


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July 15, 2004
Date

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